

PRESENTATION OF THE CLAIMS

1. (withdrawn) A nucleic acid sequence encoding a p63 cell regulatory protein, wherein said nucleic acid hybridizes under stringent conditions to a nucleic acid of SEQ ID Nos: 1-12, wherein said p63 cell regulatory protein binds a target DNA sequence.

2. (previously presented) A method for detecting malignant carcinoma, comprising:
 - (a) obtaining a tissue sample from a patient;
 - (b) determining the level of a p63 protein in said patient sample using a p63 binding protein, wherein said p63 protein comprises an amino acid sequence having at least 95% identity to an amino acid sequence set forth in any one of SEQ ID NOs: 13-24 and binds to a p53-responsive element; and
 - (c) comparing the level of said p63 protein in said patient sample with the level of said p63 protein in a control sample of cells;
wherein a lower level of said p63 protein in said patient sample as compared to the control sample is indicative of the presence of malignant carcinoma.

3. (original) A method of claim 2, wherein said malignant carcinoma is carcinoma of the cervix, breast, salivary gland and/or prostate gland.

4. (previously presented) A method of claim 2, wherein said control sample is selected from the group comprising basal epithelial cells, immature squamous cells, ME 180, sub-columnar reserve cells and human foreskin keratinocytes.

5. (previously presented) A method of claim 2, wherein the level of said p63 protein is determined by a method selected from the group comprising immunoblotting, immunoprecipitation, and sandwich immunoassay.

6. (previously presented) A method for detecting cancer in tissues containing sub-columnar reserve cells, comprising:

- (a) obtaining a tissue sample from a patient;
- (b) determining the level of a p63 protein in said patient sample using a p63 binding protein, wherein said p63 protein comprises an amino acid sequence having at least 95% identity to an amino acid sequence set forth in any one of SEQ ID NOs: 13-24 and binds to a p53-responsive element; and
- (c) comparing the level of said p63 protein in said patient sample with the level of said p63 protein in a control sample of cells;

wherein a lower level of said p63 protein in said patient sample as compared to the control sample is indicative of the presence of cancer in said tissues.

7. (original) A method of claim 6, wherein said tissue containing sub-columnar reserve cells is selected from the group comprising cervical tissue, breast tissue, and/or prostate gland tissue

8. (original) A method of claim 6, wherein said tissue containing sub-columnar reserve cells is selected from the group comprising kidney, testis, adrenal gland, brain, spleen, and thymus.

9. (original) A method of claim 6, wherein said control sample is selected from the group comprising basal epithelial cells, immature squamous cells, ME 180 and human foreskin keratinocytes.

10. (previously presented) A method for distinguishing cervical squamous carcinoma from cervical small cell undifferentiated carcinoma, comprising:

- (a) obtaining a cervical tissue sample from a patient;

(b) determining the level of a p63 protein in said patient sample using a p63 binding protein;

(c) comparing the level of said p63 protein in said patient sample with the level of said p63 protein in a control sample of cervical squamous carcinoma cells; wherein a lower level of said p63 protein in said patient sample as compared to the control sample is indicative of small cell undifferentiated carcinoma.

11. (withdrawn) A kit for diagnosing malignant carcinoma comprising:

- (a) a sample collecting means; and
- (b) a p63 PCR primer pair.

12. (withdrawn) A kit of claim 11, wherein said primer pair is selected from the group comprising TAp63-specific primer pair and a Δ Np63-specific primer pair.

13. (original) A kit for diagnosing malignant carcinoma comprising a p63 specific antibody.

14. (original) A kit of claim 13, wherein said antibody is selected from the group comprising a TAp63-specific antibody and a Δ Np63-specific antibody.

15. (previously presented) The method of claim 2, wherein said p63 protein is selected from the group consisting of TAp63 α (SEQ ID NO: 13), TAp63 β (SEQ ID NO: 14), TAp63 γ (SEQ ID NO: 15), Δ Np63 α (SEQ ID NO: 16), Δ Np63 β (SEQ ID NO: 17) and Δ Np63 γ (SEQ ID NO: 18).

16. (previously presented) The method of claim 10, wherein the level of said p63 protein is determined by a method selected from the group comprising immunoblotting, immunoprecipitation, and sandwich immunoassay.

17. (previously presented) The method of claim 10, wherein said p63 protein is selected from the group consisting of TAp63 α (SEQ ID NO: 13), TAp63 β (SEQ ID NO: 14), TAp63 γ (SEQ ID NO: 15), Δ Np63 α (SEQ ID NO: 16), Δ Np63 β (SEQ ID NO: 17) and Δ Np63 γ (SEQ ID NO: 18).

18. (previously presented) A method for distinguishing benign prostate lesions from malignant prostate lesions, comprising:

- (a) obtaining a prostate tissue sample from a patient;
- (b) determining the level of a p63 protein in said patient sample using a p63 binding protein, wherein said p63 protein comprises an amino acid sequence having at least 95% identity to an amino acid sequence set forth in any one of SEQ ID NOs: 13-24 and binds to a p53-responsive element; and
- (c) comparing the level of said p63 protein in said patient sample with the level of said p63 protein in a control sample of basaloid prostate cells;

wherein a lower level of said p63 protein in said patient sample as compared to the control sample is indicative of a malignant prostate lesion.

19. (previously presented) The method of claim 18, wherein the level of said p63 protein is determined by a method selected from the group comprising immunoblotting, immunoprecipitation, and sandwich immunoassay.

20. (previously presented) The method of claim 19, wherein said p63 protein is selected from the group consisting of TAp63 α (SEQ ID NO: 13), TAp63 β (SEQ ID NO: 14),

TAp63 γ (SEQ ID NO: 15), Δ Np63 α (SEQ ID NO: 16), Δ Np63 β (SEQ ID NO: 17) and Δ Np63 γ (SEQ ID NO: 18).

21. (previously presented) The method of claim 19, wherein the level of said p63 protein in said patient sample is at least about 2000-fold lower than the level of p63 protein in said control sample.

22. (withdrawn) The method of claim 21, wherein said p63 gene product is Δ Np63 mRNA.

23. (previously presented) The method of claim 2, wherein said p63 binding protein is a p63 specific antibody.

24. (previously presented) The method of claim 2, wherein said p63 protein has an amino acid sequence at least 98% identical to an amino acid sequence set forth in anyone of SEQ ID NOs: 13-24.

25. (previously presented) The method of claim 6, wherein said p63 binding protein is a p63 specific antibody.

26. (previously presented) The method of claim 6, wherein said p63 protein has an amino acid sequence at least 98% identical to an amino acid sequence set forth in anyone of SEQ ID NOs: 13-24.

27. (previously presented) The method of claim 10, wherein said p63 binding protein is a p63 specific antibody.

28. (previously presented) The method of claim 10, wherein said p63 protein has an amino acid sequence at least 98% identical to an amino acid sequence set forth in anyone of SEQ ID NOs: 13-24.

29. (previously presented) The method of claim 18, wherein said p63 binding protein is a p63 specific antibody.

30. (previously presented) The method of claim 18, wherein said p63 protein has an amino acid sequence at least 98% identical to an amino acid sequence set forth in anyone of SEQ ID NOs: 13-24.